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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,058	04/30/2001	Jay K.. Bass	10004190-1	4485

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/846,058	Applicant(s) BASS ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 28-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,29,31,35 and 39-45 is/are allowed.
- 6) ☒ Claim(s) 1-9,30,32-34,36 and 46 is/are rejected.
- 7) ☒ Claim(s) 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

1. The Response filed April 22, 2005 is acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

3. Claims 1-9 and 27-46 were pending. Applicants amended claims 1, 4, 28, 45 and 46. In addition, Applicants canceled claim 27. Therefore, claims 1-9 and 28-46 are pending and examined on the merits.

Withdrawn Objections and/or Rejections

4. The objections to claims 4 and 27 are withdrawn in view of Applicants' amendments and/or arguments. The Liu et al. rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are withdrawn in view of Applicants' amendments and/or arguments. The Indermuhle et al. rejection under 35 U.S.C. § 103(a) is withdrawn in view of Applicants' arguments and/or submission of data with regard to common ownership of the Cattell patent. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Objections to the Claims

5. Claims 37 and 38 are objected to because of the following informalities:
- A. Claims 37 and 38 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims Rejections - 35 U.S.C. 102

6. Claims 1-9, 30, 32-34, 36 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Indermuhle et al. (US Patent Application Publication 2001/0036674 A1) (Filed on **February 23, 2001**).

For *claims 1, 8-9*, Indermuhle et al. (see entire document) disclose methods for making and using “pillar” biochips including the use of “elongated” pillars (see Indermuhle et al., abstract; see also figures 24-25), which anticipates the claimed invention. For example, Indermuhle et al. disclose (a) comparing the height uniformity of a first direction and a second direction across a substrate to identify a first direction having higher height uniformity than a second direction, wherein said first and second directions are planar to said substrate (e.g., see Indermuhle et al., figure 24). For example, the top of element 132 in figure 24 displays a rectangle wherein a direction that is parallel to the longer edge of the rectangle (i.e., the direction labeled “Y” in figure “B” on page 4 of the 2/8/05 rejection) has a higher height uniformity than a direction that is

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parallel to the shorter edge of the rectangle (i.e., the direction labeled “X” in figure “A” on page 3 of the 2/8/05 rejection).

Here, both directions (i.e., X and Y) are in the plane of the substrate, but the “Y” direction (see figure B on page 4 of the 2/8/05 rejection) has higher height uniformity because the top of the rectangular pillar extends almost continuously across the entire length of the substrate without any variation in the height. In contrast, the “X” direction (see figure A on page 3 of the 2/8/05 rejection) extends across many pillars (e.g., elements 132 and 135; see also figure 24 wherein “9” 132 pillars are shown), spaces that separate the pillars (e.g., element 134 in figure 24), and many channel defining walls (e.g., “2” 135 pillars are shown in figure 24). Thus, the “height” is less uniform proceeding along the “X” direction than the “Y” direction (compare figures A and B on page 3 and 4 of the 2/8/05 rejection) because the height changes from pillar (i.e., element 132) to space between the pillars (i.e., element 134 in figure 24) to channel defining wall elements (i.e., element 135) (see also figure A above wherein vertical “arrows” depict all the changes in height as one proceeds along the “X” direction). In addition, the X and Y directions have been “visually compared” because figure 24 shows the “alignment” of the top piece (e.g., elements 130 and 133) parallel to the elongated axis of the pillars (e.g., elements 132 and 135). That is the top piece only “fits” in “one direction” and thus the heights must be “visually compared” in order to make this fit and/or alignment as explicitly shown in figure 24 or, in the alternative, the “comparison” was inherently made at the “fitting” and/or “design” stages (i.e., when the plates were put together OR when the bottom plate was individually fabricated). That is, the plates were designed to “fit

together”, which takes into account a comparison of the heights along the “X” and “Y” directions to insure that the top plate fits into the bottom plate both when the plates were made and when the plates are actually fitted together. If this were not the case, then the plates wouldn’t fit together and sample would be placed in the “wells” between the pillars as a result of misalignment. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

In addition, Indermuhle et al. disclose (b) placing different chemical moieties in rows on the substrate, where said rows are more closely aligned with the first direction than the second direction (e.g., see Indermuhle et al., figure 24, wherein element 133 is used to “dispense” chemical on the top of the elongated pillars “rows” (i.e., element 132) that are parallel (i.e., closely aligned to the first direction); see also page 2, column 2, paragraph 44 which discloses numerous chemical moieties that can be deposited on the pillar e.g., antibody/antigen, enzyme/substrate, etc.). In addition, Indermuhle et al. placing the different chemical moieties in rows on the substrate wherein said rows each contain a plurality of different chemical moieties (e.g., see figure 3 where the “plurality of different chemical moieties” are represented by elements 65, 66 and 67; see also figure 4 showing elements 75 and 75; see also page 2, column 2, paragraph 44, “More

specifically, interactions between the following components may be analyzed using embodiments of the invention: antibody/antigen [i.e., the antibody + antigen represents a “plurality” of different chemical moieties], antibody/hapten [i.e., the antibody + hapten represents a “plurality” of different chemical moieties] ... repressor/inducer [i.e., the repressor + induce represent a plurality of different chemical moieties] ... and the like”). The layers of silicon oxide (i.e., element 61), titanium oxide (i.e., element 62), polylysine or polyethylene glycol (i.e., element 64) in addition to the biotin (i.e., element 65), streptavidin (i.e., element 66), second adaptor biotin (i.e., element 67) and antibody (i.e., element 68) also fall within the scope of a plurality of different chemical moieties (e.g., see page 6, paragraph 77, “An interlayer 61 [referring to figure 3] including an oxide such as silicon oxide is at the top surface of the pillar 60. The interlayer 61 may be used to bind the coating layer 62 to the pillar 60. The coating layer 62 may include another oxide such as titanium oxide. An affinity structure 69 is on the coating layer 62. The affinity structure 69 may include a monolayer 64 with organic molecules such as polylysine or polyethylene glycol ... A set of molecules including a first adaptor molecule 65 such as biotin, an affinity tag 66 such as avidin or streptavidan, a second adaptor molecule 67 such as biotin, and a capture agent 68 such as an antibody are linked together ... it is understood that in embodiments of the invention, many such sets of molecules may be present on the monolayer 64.”).

Finally, Indermuhle et al. disclose the fabrication of an array of multiple features of different chemical moieties on the substrate surface (e.g., see Indermuhle et al., figure 24 disclosing the array of pillars on the surface wherein various chemicals are spotted on

said surface; see also page 2, column 2, paragraph 44; see also figures 2-4; see also page 3, column 2, paragraph 55). Also note that the “first” and “second” directions are perpendicular to the edges of the substrate (i.e., they are perpendicular to each other).

For *claim 2*, Indermuhle et al. disclose biopolymers including proteins, DNA and carbohydrates (e.g., see Indermuhle et al., page 2, column 2, paragraph 44).

For *claim 3*, Indermuhle et al. disclose measuring the thickness of the substrate at different positions (e.g., see Indermuhle et al., figure 24 wherein the thickness of the substrate is measured at each element 132 in order to fit this protrusion within the dispenser at each element 133).

For *claims 4, 32, 33 and 46*, Indermuhle et al. disclose receiving a substrate from a remote location (e.g., see Indermuhle et al., figure 24, elements 130 and 133 wherein dispenser 133 is the remote location). Indermuhle et al. further disclose receiving from a remote location in association with the substrate, an identification of a first direction across the substrate surface along which the substrate surface has a higher height uniformity than along a second direction across the substrate, wherein said first and second directions are planar to said substrate (e.g., see claim 1 above; see also Indermuhle et al., figure 24 wherein element 132 fits into or is “identified” or “recognized” by element 133 at each position on the substrate and this recognition is based on “shape”). In addition, Indermuhle et al. disclose placing chemical moieties on the substrate so as to provide features thereon along rows more closely aligned with the first direction than the second direction (e.g., see Indermuhle et al., figure 24, wherein element 133 is used to “dispense” chemical on the top of the elongated pillars that are

parallel i.e., closely aligned to the first direction; see also page 2, column 2, paragraph 44 which discloses numerous chemical moieties that can be deposited on the pillar e.g., antibody/antigen, enzyme/substrate, etc.). Finally, Indermuhle et al. disclose the fabrication of an array of multiple features of different chemical moieties on the substrate surface (e.g., see Indermuhle et al., figure 24 disclosing the array of pillars on the surface wherein various chemicals are spotted on said surface; see also page 2, column 2, paragraph 44; see also figures 2-4; see also page 3, column 2, paragraph 55).

For *claims 5, 30 and 36*, Indermuhle et al. also disclose additionally associating with the array an identification as to the direction of the rows and forwarding the array and associated identification to a remote location (e.g., see figure 24, wherein the identification of the direction of the rows is forwarded to the remote location of the dispenser chip so that the two chips can be properly aligned).

For *claims 6-7, and 34*, Indermuhle et al. disclose “aligning” the housing for the substrate, which may include a wide variety of different dispensers known in the industry (e.g., see page 8, column 2, paragraphs 94-97). Indermuhle et al. further disclose the use of alignment marks or pins (e.g., see page 9, column 2, paragraph 104) and/or the identification of particular shapes like the “rectangular” pins (e.g., see figure 24). Other identifiers are also disclosed including various types of markings (e.g., see page 9, paragraph 105).

Response

7. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed

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persuasive for the following reasons. Please note: that the above rejection has been modified from its original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue, "As illustrated in Indermuhle's Figs. 8, 9 and 25, Indermuhle places a single chemical moiety on the top of each pillar by essentially 'dipping' the pillar into a reagent trough ... At no point does Indermuhle disclose depositing a row of different chemical moieties onto the top of a rectangular pillar. Since Indermuhle's technology relies on 'dipping' pillars into reagent troughs, this would be impossible ... Indermuhle simply does not provide this feature because it would involve depositing different chemical moieties lengthwise along the top of a rectangular pillar" (e.g., 4/22/05 Response, pages 7-8).

This is not found persuasive for the following reasons:

The Examiner respectfully disagrees. Indermuhle et al. disclose depositing on a row of elongated pillars (e.g., see elements 132 in figure 24) a plurality of different chemical moieties (e.g., see figure 3 wherein, for example, layers of silicon oxide (i.e., element 61), titanium oxide (i.e., element 62), polylysine or polyethylene glycol (i.e., element 64) in addition to the biotin (i.e., element 65), streptavidin (i.e., element 66), second adaptor biotin (i.e., element 67) and antibody (i.e., element 68) constitute the "plurality" of different moieties. Please note other examples are also disclosed as set forth in the newly amended rejection above.

In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "depositing different chemical moieties lengthwise" as shown, for example, in Applicants' picture at the bottom of page 7 of the 4/22/05 Response) are not recited in the rejected claim(s).

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

Allowable Subject Matter

8. Claims 28, 29, 31, 35 and 39-45 are allowed. In addition, claims 37 and 38 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims to overcome the objections to being dependent upon a rejected base claim.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

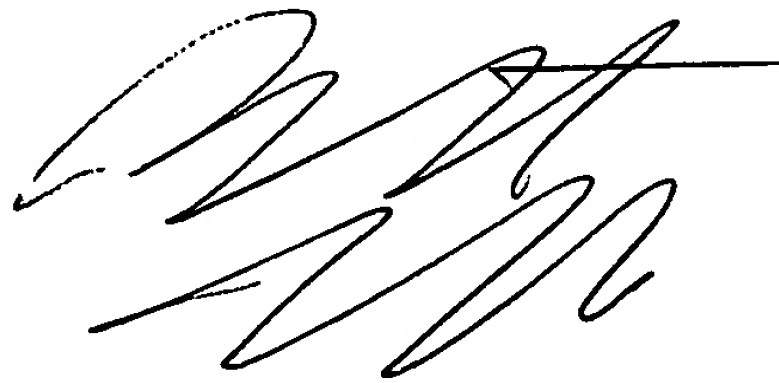
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Jon D. Epperson, Ph.D.

July 3, 2005

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'B. Celsa', is written over the printed name and title of the examiner.